UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/609,543	07/03/2000	Michael Jeffers	15966-557 CIP	3281

7590 04/17/2002

MIntz Levin Cohn Ferris Glovsky and Popeo PC
One Financial Center
Boston, MA 02111

EXAMINER
SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
1647	10

DATE MAILED: 04/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/609,543	JEFFERS et al.
Examiner	**Art Unit**
Christine Saoud	1647

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Feb 7, 2002* .

2a) [ ] This action is **FINAL.** 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *1-62* is/are pending in the application.

4a) Of the above, claim(s) *6-40, 42-45, and 47-62* is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *1-5, 41, and 46* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____ .
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) [X] Notice of References Cited (PTO-892)
16) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) [ ] Information Disclosure Statement(s) (PTO-1449) Paper No(s).
18) [ ] Interview Summary (PTO 413) Paper No(s).
19) [ ] Notice of Informal Patent Application (PTO-152)
20) [ ] Other:

DETAILED ACTION

Election/Restriction

1. Claims 1-62 are pending in the instant application. Claims 6-40, 42-45 and 47-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Specification

2. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

3. The abstract of the disclosure is objected to because it uses the term "novel" and refers to speculative applications of the invention. Correction is required. See MPEP § 608.01(b).

Claim Objections

4. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 recites a "fragment of a polypeptide described in claim 1", wherein part (e) of claim 1 is already directed to fragments of parts (a) - (d). Therefore, claim 2 does not appear to be further limiting.

5. Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 5 recites "wherein one or more of any amino acid specified in SEQ ID NO:2 is changed to provide a conservative substitution" and ultimately depends from claim 1 which recites "85% identical". Therefore, claim 5 is broader than claim 1, in that there is no upper limit on the number of substitutions, and can then encompass greater variability than "85%".

6. Claim 46 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

claim(s) in independent form. The recitation of "a kit" fails to place any limitation on the pharmaceutical composition of 41, therefore, it fails to further limit the subject matter of the previous claim. Additionally, it would appear that a "kit" would require more than a single element.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-5, 41 and 46 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of the nucleic acid, the encoded protein or the significance of either.

It is clear from the instant specification that the "FGF-CX" protein (SEQ ID NO:2) described therein is what is termed an "orphan protein" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this protein, and the nucleic acid encoding it, may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148

U.S.P.Q. 689 (Sus. Ct. 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to a protein of as yet undetermined function or biological significance. There is absolutely no evidence of record or any line of reasoning that would support a conclusion that the "FGF-CX" protein of the instant application could be used in a method of diagnosing, treating, preventing, or delaying a tissue proliferation-associated disorder, such as "tumors, restenosis, psoriasis, Dupuytren's contracture, diabetic complications, Kaposi sarcoma, and rheumatoid arthritis" (see page 6, lines 3-7 of the specification), in a method of "treating a pathological state in a mammal" by administering the polypeptide (see page 5, line 6), in a method of "promoting growth of cells in a subject" wherein the cells are "in the vicinity of a wound, cells in the vascular system, cells involved in hematopoiesis, cells involved in

erythropoiesis, cells in the lining of the gastrointestinal tract, and cells in hair follicles" (see page 5, lines 15-21), in "methods of diagnosing the presence or amounts of these compositions, in screening for and identifying therapeutic agents related to FGF-CX-associated pathologies, and in methods of treatment of various kinds of malignancy" (see sentence spanning pages 17-18), for use in screening assays, detection assays, predictive medicine, and methods of treatment (see sentence spanning pages 67-68), for stimulation of fibroblasts for use in wound healing (see page 76, lines 29-30), for stimulation of hematopoietic cells, immune system cells, and vascular smooth muscle cells, as well as for treating bone fractures and osteoporosis (see page 77, lines 1-3), diagnosis of cerebral tumors (page 77, lines 3-4), and for treatment of cancer (page 77, lines 9-13). Neither the specification nor the prior art demonstrates a causal correlation or nexus of the claimed polypeptide with any of the conditions or disorders contemplated by the instant specification, therefore, there is no evidence of record that would provide for a method of treating/diagnosing any of the listed conditions or disorders. There is absolutely no evidence of record or any line of reasoning that would support a conclusion that the "FGF-CX" protein of the instant application is involved in regulating growth and/or differentiation of any *particular* cell population. The record fails to indicate any evidence of any of these biological activities, and it would appear that until some actual and specific significance can be attributed to the protein identified in the specification as FGF-CX, the gene encoding it, or the antibody that binds it, the instant invention is incomplete. The instant specification refers to "FGF-CX - like activities and physiological functions", but fails to describe what these activities or functions are. The specification asserts that the claimed protein will have activities similar to other FGF proteins

based on amino acid sequence similarity, but it is not clear or predictive which activity of the FGF family will be possessed by the claimed protein based on structural similarity alone. The protein of the instant specification is a compound which is known to share some structural similarity to the FGF family of proteins which are known in the art to have biological significance in regulation of cell proliferation, differentiation, and function based on sequence similarity to members of the FGF-family. However, as indicated in Galzie et al. (Biochem. Cell Biol. 75: 669-685, 1997), the FGF family is complex and diverse (see abstract). Table 1 of Galzie et al. details the biological significance of the first 9 members of this protein family, wherein none of the associated functions are found in common with any other family member. In the absence of a knowledge of the biological significance of "FGF-CX", there is no immediately obvious patentable use for it or the receptor which binds it. The disclosed protein only shares approximately 70% amino acid sequence similarity/identity with the most closely related protein of the prior art. Based on this degree of sequence similarity, it is unlikely and unpredictable if any one biological activity of the prior art will be possessed by the claimed protein. Furthermore, the prior art of record demonstrates that the biological function of the protein family to which the disclosed protein is said to be a member is so diverse, that one could not predict which biological activity is possessed by the disclosed protein based on structural similarity alone, especially since all the members share structural similarity, but not functional similarity. To employ the instant invention in any of the disclosed methods would clearly be using it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability. Since the

instant specification does not disclose a credible "real world" use for the claimed invention, it is incomplete and, therefore, does not meet the requirements of 35 U.S.C. §101 as being useful.

The instant specification provides data on expression of the claimed protein, indicating that it is expressed in normal cerebellum, as well as in several human tumor cell lines without being expressed in corresponding normal tissues. The specification provides a chromosomal location for the FGF-CX and "[e]xpression of heterologous FGF-CX in NIH 3T3 cells is found to induce their transformation and tumorigenicity" (see page 17, lines 15-16). However, these disclosed properties of the claimed protein, expression pattern and ability to transform fibroblast cells in culture does not provide a specific, substantial and credible utility for the claimed polypeptides. Expression of the claimed polypeptide in cancer tissue does not establish a nexus between the claimed protein and cancer growth. Expression of the claimed polypeptide could just as likely be a result of the cancer, and not a causative agent, therefore one of ordinary skill in the art could not target the claimed polypeptide for treatment of the cancer. The instant specification fails to teach that the claimed polypeptide is diagnostic for any specific cancer, as it is found in normal and diseased tissue. The instant specification teaches that administration of the polypeptide stimulates proliferation of fibroblasts in culture, but these cells also lose contact inhibition, meaning that the cells take on a transformed phenotype. Therefore, the claimed polypeptide would not be considered useful for wound healing as asserted in the specification. Page 101 of the instant specification states "[s]pecific disease indications where therapeutic targeting of FGF-CX might be applied include adenocarcinomas of the colon, prostate, lung, kidney, uterus, breast, bladder, ovary" (see lines 26-28). However, in the absence of a nexus or

correlation with a particular disease or cancer, the instant specification does not disclose a credible "real world" use for the claimed invention, it is incomplete and, therefore, does not meet the requirements of 35 U.S.C. §101 as being useful.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-5, 41 and 46 are rejected under 35 U.S.C. §112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. §101.

11. Claims 1-5, 41 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites "a mature form of an amino acid sequence", "a variant of a mature form of an amino acid sequence", claim 3 recites "wherein said polypeptide is a naturally occurring allelic variant", and claim 4 recites "wherein the variant is the translation of a single nucleotide polymorphism". However, the instant specification fails to provide a written description of that subject matter which is being claimed.

First, the recitation of "a mature form" is directed to a very specific species which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The structure of a "mature form" cannot be predicted on the basis of the amino acid sequence of the entire protein since the protein may be proteolytically cleaved in vivo, as well as being differentially processed based on which in tissue the protein is expressed. The claims are directed to a species of protein, the structure of which cannot be determined or predicted from full-length amino acid sequence and the specification does not evidence isolation or conception of the structure of the "a mature form of an amino acid sequence" or a variant thereof, therefore, the specification does not provide an adequate written description of a mature protein, and thus the claimed invention, to the extent that it reads upon mature protein was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Second, the recitation of "naturally occurring allelic variant" is directed to a specific molecule for which the instant specification fails to describe the molecule in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The structure of a "naturally occurring allelic variant" cannot be predicted on the basis of the amino acid sequence of SEQ ID NO:2 since there is no disclosure of where the variation occurs in the sequence of SEQ ID NO:2 and is still a "naturally occurring" protein. The claims are directed to a species of protein, the structure of which cannot be determined or predicted from the disclosed amino acid sequence and the

specification does not evidence isolation or conception of the structure of the "naturally occurring allelic variant", therefore, the specification does not provide an adequate written description of the claimed subject matter, and thus the claimed invention, to the extent that it reads upon a "naturally occurring variant" was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Third, the recitation of "wherein the variant is the translation of a single nucleotide polymorphism" lacks written description because there is no written description of "a single nucleotide polymorphism" (SNP). In so far as the claim encompasses an amino acid sequence which differs from SEQ ID NO:2, the specification lacks a written description of the structure of these sequences and the structure cannot be determined or predicted from the disclosed amino acid sequence. The specification does not evidence isolation or conception of the structure of an amino acid sequence which is the "translation of a single nucleotide polymorphism", therefore, the specification does not provide an adequate written description of the claimed subject matter, and thus the claimed invention, to the extent that it reads upon a variant resulting from the "translation of a single nucleotide polymorphism" was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in

possession of the invention. The invention is for purposes of the 'written description' inquiry, whatever is now claimed." (See Vas-Cath at page 1116.)

With the exception of very particular amino acid sequences which are disclosed in the instant application, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptide molecules and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of protein expression. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The specific molecular structure is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) The instant claims are directed to a structure, which could be made, but for which, there is no written description. As in Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class because the specification provided only the bovine sequence. In the instant situation, the specification only provides the full length protein, but fails to provide a description of the "broad class" of mature forms of polypeptides, naturally occurring

allelic polypeptide variants and protein variants which are the result of translation of a SNP, regardless of whether they could be made or isolated.

12. Claims 1-5, 41 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 includes embodiments of polypeptides having at least 85% sequence identity to SEQ ID NO:2 and claim 5 encompasses variants with no degree of sequence identity. The instant specification fails to describe polypeptides which meet these limitations of the claims. First, the instant specification teaches a single example of a polypeptide (SEQ ID NO:2), and fails to teach any other polypeptides having at least 85% identity, or variants, or allelic variants of SEQ ID NO:2. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a protein which has the amino acid sequence of SEQ ID NO:2. The subject matter which is claimed is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are directed to polypeptide which have sequence identity or to variants of the disclosed polypeptide of SEQ ID NO:2. First, the claims are not limited to any particular polypeptide, in

that the claims are also directed to variant forms thereof. The specification only describes a single polypeptide and fails to teach or describe any other molecules which meet the structural limitations of the claims. The breadth of the claims is such that the claims encompass polypeptides from other species, related polypeptides and variants which have yet to be described. There is a lack of guidance or teaching regarding structure and function of the polypeptide because there is only a single example of a polypeptide provided in the specification and because there is no guidance found in the prior art for this specific polypeptide.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the polypeptide of SEQ ID NO:2. The specification does not provide a complete structure of those molecules which have at least 85% sequence identity to SEQ ID NO:2, or to variants of the disclosed polypeptide of SEQ ID NO:2. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus because the specification teaches a single embodiment. Therefore, the claims are directed

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites "conservative substitution". However, "conservative substitution" is a relative recitation in that a number of properties could be conserved with amino acid substitution, including but not limited to amino acid structure of the amino acid being replaced, overall protein structure, and protein function wherein function could be defined as immunogenicity, cell specificity, proliferative activity, etc. Without knowing which property is the target of the conservation, the metes and bounds of a "conservative substitution" are unclear.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1-2, 5, 41 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Nauro et al. (U.S. Pat. No. 5,512,460).

Nauro et al. disclose and teach a polypeptide which meets the structural limitations of the instant claims in that it could be considered a "variant" of SEQ ID NO:2 (see SEQ ID NO:11 of Nauro et al.) as well as being an isolated polypeptide comprising an amino acid sequence which is a fragment of the sequence of SEQ ID NO:2 (there is no size limitation on "fragment", therefore, a single amino acid in common meets this structural limitation). The polypeptide of Nauro et al. appears to meet the structural limitation of claim 5 in light of the indefiniteness of the recitation "conservative substitution". As claim 5 recites "a variant polypeptide, and wherein one or more of any amino acid specified in SEQ ID NO:2 is changed to provide a conservative substitution", it would appear that this claim encompass any protein which has an unlimited number of amino acid substitutions, therefore, the polypeptide of Nauro et al. meet these structural limitations as well.

Conclusion

17. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Christine J. Saoud, Ph.D., whose telephone number is (703) 305-7519. The Examiner can normally be reached on Monday to Friday from 7AM to 3PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §§ 1.6(d) and 1.8). NOTE: If Applicant *does* submit a paper by fax, the

original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternate number. Official papers filed After Final rejection filed by fax should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 15, 2002

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud